



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Compositions, Devices and Processes for Production and Delivery of Cell Grafts of Manufactured Retinal Pigment Epithelium Cell(s) Alone, or in Combination with Photoreceptor Cells, and on a Biodegradable Support Scaffold Transplanted Subretinally for Intra-Ocular Ophthalmic Treatment of Conditions of Degeneration, Dysfunction or Terminal Injury of Retinal Pigment Epithelium and/or Photoreceptors in Humans

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Opsi Therapeutics, LLC, (“Opsi”) located in Madison Wisconsin and its affiliate, FUJIFILM Cellular Dynamics, Inc.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before **[INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Edward Fenn., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: Tedd.Fenn@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

- PCT Patent App. No. PCT/US2015/039932, filed 07/10/15 (NIH Ref. E-192-2014-1-PCT-01); United States Patent App. No. 15/325,584, filed 01/11/17 (NIH Ref. E-192-2014-1-US-02); Australia Patent App. No. 2015287692, filed 07/10/15 (NIH Ref. E-192-2014-1-AU-03); Canada Patent App. No. 2954762, filed 07/10/15 (NIH Ref. E-192-2014-1-CA-04); PEC Patent App. No. 15741462.4, filed 07/10/15 (NIH Ref. E-192-2014-1-EP-05); India Patent App. No. 01717003244, filed 01/30/17 (NIH Ref. E-192-2014-1-IN-06); Japan Patent App. No. 2017-501212 Filed 01/10/17 (NIH Ref. E-192-2014-1-JP-07); each entitled “Surgical Tool and Method for Ocular Tissue Transplantation”;
- United States Patent App. No. 62/215,579, filed 09/08/15 (NIH Ref. E-212-2015-0-US-01); PCT Patent App. No. PCT/US2016/050543, filed 09/07/16 (NIH Ref. E-212-2015-0-PCT-02); Australia Patent App. No. 2016321170, filed 03/21/18 (NIH Ref. E-212-2015-0-AU-03); Canada Patent App. No. 2997952, filed 09/07/16 (NIH Ref. E-212-2015-0-CA-04); EPC Patent App. No. 16766444.0, filed 09/07/16 (NIH Ref. E-212-2015-0-EP-05); Japan Patent App. No. 2018-512373, filed 03/07/18 (NIH Ref. E-212-2015-0-JP-06); United States Patent App. No. 15/758,314, filed 03/07/18 (NIH Ref. E-212-2015-0-US-07); China patent application No. 201680060872.4, filed 04/18/2018 (NIH Ref. pending); Korea patent application No. 1020187009942, file 04/06/2018 (NIH Ref. pending); each entitled “Method for Reproducible Differentiation of Clinical-Grade Retinal Pigment Epithelium Cells”;
- United States Provisional Patent App. No. 62/419,804, filed 11/09/16 (NIH Ref. E-293-2016-0-US-01); PCT Patent App. No. PCT/US2017/060672, filed 11/08/17 (NIH Ref. E-293-2016-0-PCT-02); Australia Patent App. No. 2017359336, filed 11/08/17 (NIH Ref. E-293-2016-0-AU-04); Canada Patent App. No. 3043174, filed 11/08/17 (NIH Ref. E-293-2016-0-CA-05); EPC Patent App. No. 17801272.0, filed 11/08/17 (NIH Ref. E-293-2016-0-EP-06); Japan Patent App. No. pending (NIH Ref. E-293-2016-0-JP-07); United States Patent App. No. 16/348,855, filed 05/09/2019 (NIH Ref. E-293-2016-0-US-03); each entitled “A Surgical Clamp to Gate Large Scleral Surgery Port and Suture Alignment Tool”;
- United States Patent App. No. 62/453,148, filed 02/01/17 (NIH Ref. E-094-2016-0-US-01); PCT Patent App. No. PCT/US2018/016101, Filed 01/31/18 (NIH Ref. E-094-2016-0-PCT-02) entitled “Devices for Tissue Cryopreservation and Recovery” and; United States Patent App. No. pending (NIH Ref. E-094-2016-0-US-03); Australia Patent App. No. 2018214954 filed 01/31/18 (NIH Ref. E-094-

2016-0-AU-04); Canada Patent App. No. pending (NIH Ref. E-094-2016-0-CA-05); EPC Patent App. No. pending (NIH Ref. E-094-2016-0-EP-06); Japan Patent App. No. pending (NIH Ref. E-094-2016-0-JP-07); each “A Self-contained Cryopreservation and Recovery Device for Tissue Storage, Shipping and Recovery”;

- United States Provisional Patent App. No. 62/644,175, filed 03/16/18 (NIH Ref. E-058-2018-0-US-01) entitled “Using Machine Learning And/or Neural Networks to Validate Stem Cells and Their Derivatives for Use in Cell Therapy, Drug Discovery and Diagnostics”; PCT Patent App. No. pending (NIH Ref. E-058-2018-0-PCT-02) entitled “Using Machine Learning And/or Neural Networks to Validate Stem Cells and Their Derivatives (2-D Cells And 3-D Tissues) for Use in Cell Therapy And Tissue Engineered Products”;
- United States Patent App. No 62/769,484, filed 11/19/18 (NIH Ref. E-015-2019-0-US-01) entitled “Biodegradable Tissue Replacement Implant and its Use”;

and all U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

“The development, production and commercialization of allogeneic cell grafts of manufactured Retinal Pigment Epithelium cell(s) alone, or in combination with photoreceptor cells, and on a biodegradable support scaffold transplanted subretinally for intra-ocular ophthalmic treatment of conditions of degeneration, dysfunction or terminal injury of retinal pigment epithelium and/or photoreceptors in humans.”

The technologies relate to development of compositions, devices and processes for production and delivery of RPE-containing tissue graft therapies for treating a range of retinal function disorders, including retinal degenerative conditions in humans.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National

Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: September 26, 2019.

Richard U. Rodriguez

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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